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## **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Steven Hultquist on August 16, 2007.

2. The application has been amended as follows:

Please cancel claims 15, 17, and 18.

Please amend the claims as follows:

- 8. A method according to claim 16, in which when the comparison of the results obtained in step a) with normal values, of reference, indicates that:
- (i) the concentration of the proteins APA 1, ATPB, LKHA, K 1CR, GAMT, SODC, ALBU, and AOP2 (isoform 1), is higher than the normal reference values for said proteins in liver tissue; and/or
- (ii) the concentration of the proteins PHB1, AOP2 (isoform 2), MAT, ACDL or and SBP is lower than the normal values of reference for said proteins in liver tissue,

then, said results are indicative of the existence of NASH in the subject whose liver tissue sample has been assayed or of the existence of a susceptibility of said subject to develop NASH in the future.

14. A method of assessing a subject to identify the presence of or susceptibility to NASH in said subject, said method comprising: detecting and quantifying levels of each of a combination of

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proteins in liver tissue of said subject, said combination including the following proteins: apolipoprotein A1 (APA1), mitochondrial ATPase 13 subunit (ATPB), leukotriene A4 hydrolase (LKHA), keratin 18 (K1CR), guanidinoacetate N- methyltransferase (GAMT), superoxide dismutase (SODC), antioxidant protein 2 (AOP2) (isoforms 1 and 2), prohibitin 1 (PHB1), methionine adenosyl transferase (MAT), long-chain acyI-CoA dehydrogenase (ACDL), and selenium binding protein (SBP);

comparing levels of each of said combination of proteins to reference values that permit existence or susceptibility of NASH in said subject to be assessed;

and identifying from said comparing, the presence of NASH in said subject or the susceptibility of said subject to NASH.

- 16. An in vitro method for assessment of a liver tissue sample from a subject, to determine presence of or susceptibility to NASH in said subject, said method comprising:
- a) detecting and quantifying in said liver tissue sample the level of each of the following proteins: apolipoprotein A1 (APA1), mitochondrial ATPase 13 subunit (ATPB), leukotriene A4 hydrolase (LKHA), keratin 18 (K1CR), guanidinoacetate N-methyltransferase (GAMT), superoxide dismutase (SODC), albumin (ALBU), antioxidant protein 2 (AOP2) (isoforms 1 and 2), prohibitin 1 (PHB1), methionine adenosyl transferase (MAT), long-chain acyl-CoA dehydrogenase (ACDL), and selenium binding protein (SBP);
- b) comparing the results obtained in step a) with normal reference values for said proteins in liver tissue; and

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c) based on said comparing, determining the presence of or susceptibility to NASH in

said subject

Conclusion

3. Claims 1-5, 8, 14, and 16 are allowed.

4. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The

examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

5. Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated

information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nelson Yang Patent Examiner Art Unit 1641

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